UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE LUMIFY	Civil Action No. 21-16766 (RK) (RLS) (CONSOLIDATED) *Document Electronically Filed*

DEFENDANTS' RESPONSIVE *MARKMAN* SUBMISSION

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Other Authorities

I. INTRODUCTION

Defendants' proposed constructions of the phrases "in need of said reduction of eye redness" and "as the sole active ingredient" more closely reflect the plain language of the claims of the '600 patent. A human "in need of said reduction of eye redness" is a human "having ocular hyperemia." The existence of the "ocular hyperemia"—i.e., red eyes—is what creates the need to administer a redness-relieving eye drop. And an ocular drop comprising about 0.025% weight by volume brimonidine "as the sole active ingredient" refers to brimonidine "without any other active ingredient in the ocular drop." These constructions are simple and supported by the claims of the '600 patent, the specification, the prosecution history, and the claims of related patents.

Plaintiffs, on the other hand, effectively concede they want to change the plain meaning of the claims based on statements from the specification and prosecution history. This is apparent throughout Plaintiffs' brief. Plaintiffs argue that the disputed portions of their proposals are "critical because it captures the essence of the inventive methods" and that the prosecution history "particularly evidences how the Patentee understood" the claim terms. *See* Pl. Br. at 2. Throughout their brief, Plaintiffs argue that their constructions are derived from vague concepts such as the "context of the fully claimed method of reducing eye redness" and claim that those constructions are "consistent with the specification and prosecution history." *Id.* at 15–16. With respect to the second disputed term—"as the sole active ingredient"—Plaintiffs go so far as to argue that "Patentee clearly and unmistakably surrendered and disclaimed the use of brimonidine with any other active agent." *Id.* at 23. Put another way, Plaintiffs are affirmatively arguing that during prosecution—which occurred in 2023, fifteen years after the original patent applications claiming the same invention were filed—Patentee *changed* the scope of the invention. When, like here, a party relies on the specification of the patent and the prosecution history to try to

change the meaning of claim language, the Federal Circuit imposes a high standard. Plaintiffs have not come close to meeting that standard and the Court should reject Plaintiffs' efforts to read additional limitations and requirements into claim language simply because they are "consistent" with the "essence" of the invention, the specification, or the prosecution history.

II. LEGAL STANDARDS

Plaintiffs spend significant time emphasizing statements made in the specification and during prosecution of the '600 patent to argue for their proposed constructions. To be sure, the specification and prosecution history are important to claim construction and can (but not always) inform a disputed construction. But claim construction "must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to particularly point out and distinctly claim the subject matter which the patentee regards as his invention." *Interactive Gift Exp., Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) (internal quotations omitted). This focus on the claims themselves makes sense because black letter law makes clear "that the scope of [patents] should be limited to the invention covered by the claim, and that though the claim may be illustrated, it cannot be enlarged by the language used in other parts of the specification." *Lehigh Valley R. Co. v. Mellon*, 104 U.S. 112, 118 (1881). While other intrinsic evidence—the patent specification and prosecution history—may help to inform the meaning of the claims, "[a]ll intrinsic evidence is not equal." *Interactive Gift*, 256 F.3d at 1331. The Federal Circuit has explained that courts first "look to the claim language, as '[t]he actual words of the claim are the controlling focus.'" *Cambrian Science Corp. v. Cox Commc'ns, Inc.*, 617 Fed. App'x 989, 992 (Fed. Cir. 2015) (citing *Digital Biometrics, Inc. v. Identix, Inc.*, 149 F.3d 1335, 1344 (Fed. Cir. 1998)).

It is improper to import limitations from the specification, especially to the exclusion of certain embodiments. *Comark Commc'ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed. Cir.

1998) (rejecting a construction that would import a limitation from the specification and acknowledging the Federal Circuit's "repeated statements that limitations from the specification are not to be read into the claims"). The Federal Circuit has long referred to the reading of a limitation from the written description into the claims as "one of the cardinal sins of patent law." *AIP Acquisition LLC v. Cisco Sys., Inc.*, 714 Fed. App'x 1010, 1016 (Fed. Cir. 2017). "To avoid importing limitations from the specification into the claims," the Federal Circuit has cautioned that courts "keep in mind that the purposes of the specification are to teach and enable those of skill in the art to make and use the invention and to provide a best mode for doing so." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005). As explained by the Federal Circuit, "[m]uch of the time, upon reading the specification in that context, it will become clear whether the patentee is setting out specific examples of the invention to accomplish those goals, or whether the patentee instead intends for the claims and the embodiments in the specification to be strictly coextensive." *Id.*

For prosecution history disclaimer to apply, a party must meet a high bar that "requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable." *Omega Eng'g, Inc, v. Raytek Corp.*, 334 F.3d 1314, 1325–26 (Fed. Cir. 2003). Any alleged disavowing statements must be "so clear as to show reasonable clarity and deliberateness" and "so unmistakable as to be unambiguous evidence of disclaimer." *Id.* at 1325. "The party seeking to invoke prosecution history disclaimer bears the burden of proving the existence of a 'clear and unmistakable' disclaimer that would have been evident to one skilled in the art." *Mass. Inst. of Tech. v. Shire Pharms., Inc.*, 839 F.3d 1111, 1119 (Fed. Cir. 2016). "In determining whether a clear and unambiguous disclaimer attaches to particular claim language, it is important to consider the statements made by the applicant both in the context of the entire

prosecution history and the then-pending claims." *Id.* at 1120. Prosecution history disclaimer does not apply "[w]here the alleged disavowal is ambiguous, or even amenable to multiple reasonable interpretations." *Id.* at 1119 (internal quotations omitted).

III. ARGUMENT

A. "in need of said reduction of eye redness"

Claim Term for Construction	Defendants' Proposed Construction	Plaintiffs' Proposed Construction
"in need of said reduction of eye redness" Claims 12, 28 (language appears in Claim 1, from which the Asserted Claims depend directly)	"having ocular hyperemia"	"a human having ocular hyperemia, where such hyperemia is reduced by vasoconstriction"

The parties agree that said human "in need of said reduction of eye redness" refers to a human "having ocular hyperemia." *See, e.g.*, Pl. Br. at 16. Plaintiffs also agree that a POSA "reading the preamble together with the full claim element containing the disputed phrase" "would have understood the disputed phrase to mean that the human subject of the claimed method has ocular hyperemia." *See* Pl. Br. at 17. In other words, the parties agree that "in need of said reduction of eye redness" refers to the patient population intended by the claimed method—humans having ocular hyperemia. Therefore, the question before the Court regarding this term is simple: does the "in need of said reduction of eye redness" also mean that the eye redness "is reduced by vasoconstriction"? The answer here must be no. Importing such an efficacy limitation into the claims, where there is no support in the claims for such a limitation, is contrary to law.

Plaintiffs argue that "reading the preamble together with the full claim element containing the disputed phrase, a POSA would have understood the disputed phrase to mean

that . . . the hyperemia is actually reduced by vasoconstriction." Pl. Br. at 17. Not only would a POSA fail to make such an assumption, but interpreting the claims in this manner is contrary to established precedent. The Federal Circuit has repeatedly rejected attempts to read an effectiveness requirement into claims that do not explicitly claim effectiveness. *Iovate Health Scis., Inc., v. Bio-Engineered Supplements & Nutrition, Inc*, 586 F.3d 1376, 1382 (Fed. Cir. 2009); *Mitsubishi Chem. Corp. v. Barr Lab'ys, Inc.*, 435 Fed. App'x 927, 934–35 (Fed. Cir. 2011).

For example, in *Iovate Health*, the Federal Circuit refused to read an effectiveness requirement into the preamble because the claims "do not require any further measurement or determination of any result achieved by administering the claimed composition." *Iovate Health*, 586 F.3d at 1382. As with *Iovate*, the claims here also do not require any further measurements or determination of any result achieved by administering the ocular drop. Plaintiffs argue that the preamble would cause a POSA to understand that the claims require that "the human subject of the claimed method has ocular hyperemia and the hyperemia is actually reduced by vasoconstriction." Pl. Br. at 17. But the preamble in the claims of the '600 patent contain no such requirement or language. In fact, as Plaintiffs point out, similar arguments were raised before the Patent Office for the substantially similar preamble of the '742 patent ("method for reducing eye redness"), *see* Pl. Br. at 20, and the Patent Office rejected Plaintiffs' attempts to import an efficacy requirement there. *See Slayback Pharma LLC v. Eye Therapies, Inc.*, IPR 2022-00142, at 10–12 (P.T.A.B. May 15, 2023) ("we determine that the preamble of the claims is limiting and requires that the claimed brimonidine composition be administered with the intentional purpose of reducing eye redness, whether or not eye redness is actually reduced") (previously filed as Dkt. No. 136, Ex. A).

There should be no dispute that the preamble when read in conjunction with the rest of the claim provides context that the "said human" has ocular hyperemia. Yet Plaintiffs attempt to point to passages of the specification that disclose achieving vasoconstriction and "effective vasoconstriction," to bring those limitations into the claims. Pl. Br. at 18. But "[n]one of the cited portions of the specification suggests that efficacious treatment is a limitation of the claims." *Celgene Corp. v. Hetero Lab'ys Ltd.*, Civ. No. 17-3387-ES-MAH, 2020 WL 3249117, at *6 (D.N.J. June 16, 2020). Indeed, under Plaintiffs' interpretation, every claim with a preamble setting forth a method of treatment would require the method to be effective if the specification discussed efficacy, but precedent makes clear that is not the case. For example in *Celgene Corp.*, the patentee argued that the preamble set forth "the essence or a fundamental characteristic of the claimed invention" because the specification identified "a significant need for safe and effective methods of treating, preventing and managing cancer" and described the invention as "administering to a patient in need of such treatment or prevention a therapeutically or prophylactically effective amount." *Id.* (cleaned up). This Court rejected that argument recognizing that "the statements in the specification merely stated that the intended use or purpose of the claimed invention is to achieve 'safe and effective' treatment." *Id.*

Plaintiffs cite to *Jansen* and *Sanofi* claiming that these cases provide support for their argument; however, the courts in these cases found the preamble to limit the claim scope with respect to the intended use of the claims, not to impose any efficacy requirements. In *Jansen*, the parties disputed whether a "human in need thereof" could be construed to mean "substantially all humans." *Jansen v. Rexall Sundown, Inc.*, Civ. No. IP00-1495-C-T/G, 2002 WL 31427511, at *4 (S.D. Ind. Sept. 25, 2002). The district court reasoned that "because the original claims in the [] application already provided that the method was for treating or preventing anemia in

'humans,' the language 'human in need thereof' must mean something more than simply 'human.'" *Id.* at *5. To understand the meaning of the phrase "human in need thereof," the court turned to the preamble for guidance. *Id.* In deciding that the preamble "[a] method of treating or preventing macrocytic-megaloblastic anemia in humans" is limiting, the court found that the claims were directed to a method to be practiced for "**the purpose of** treating or preventing macrocytic-megaloblastic anemia in a human." *Id.* at 6 (emphasis added). In affirming that construction, the Federal Circuit explained that the method must be "administered to a human **with a recognized need** to treat or prevent macrocytic-megaloblastic anemia." *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1334 (Fed. Cir. 2003) (emphasis added). Neither court construed the claims to include a limitation that the method actually worked—only that it be administered to a human with a recognized need for treatment or prevention.

In *Sanofi Mature IP v. Mylan Lab'ys Ltd.*, the Federal Circuit considered the preamble "[a] method of increasing survival comprising administering to a patient in need thereof." 757 Fed. App'x 988, 989 (Fed. Cir. 2019). The Federal Circuit noted that "the phrase 'patient in need thereof' . . . relies on the preamble for antecedent basis" and that the "preamble expresses the intentional purpose[–increasing survival–]for which the method must be performed." *Id.* at 993 (internal quotations omitted). The Federal Circuit did not endorse importing an efficacy requirement into the claims and remanded the case to the PTAB. On remand, the PTAB expressly stated that they "have been instructed to treat the preamble of claim 31 'as an additional limitation of' the claim that 'require[s] increasing survival' as the 'intentional purpose . . . for which the [recited] method must be performed." *Mylan Lab'ys Ltd. v. Aventis Pharma S.A.*, IPR2016-00712, 2019 WL 5430242, at *5 (P.T.A.B. Oct. 22, 2019). Under

Plaintiffs' own case law, the claimed method would only need to be performed with the intention of reducing eye redness and not with the requirement that actual reduction occur.

Plaintiffs' argument that the "in need of" is a "core part of a manipulative step in the claimed method" misses the point. *See* Pl. Br. at 15. Consistent with other courts who have construed the term "in need of", this phrase simply defines the patient population to be treated with the claimed method—those who need reduction of eye redness. *See, e.g.*, *Eli Lilly and Co. v. Eagle Pharms., Inc.*, Civ. No. 17-1293-MSG, 2019 WL 1299212, at *6 (D. Del. Mar. 21, 2019) (refusing to construe "'a patient in need of chemotherapeutic treatment' as a patient 'receiving effective amounts of the compounds or drugs for chemotherapy'" and construing "[a] patient 'in need of chemotherapeutic treatment' just [as] a patient who needs chemotherapy"); *Jansen*, 342 F.3d at 1334 (construing "a human in need thereof" to be "a human with a recognized need to treat or prevent macrocytic-megaloblastic anemia"). In other words, the manipulative step is limiting the administration of brimonidine to a particular group of patients—namely, those with red eyes.

Plaintiffs also argue that the specification and prosecution history "describe and clarify that the '600 patent methods require administering brimonidine as claimed to a human subject's hyperemic eyes to affirmatively reduce the hyperemia by vasoconstriction." Pl. Br. at 18. Plaintiffs' attempt to import specific claim limitations found in some embodiments described in the specification is improper. *Comark Commc'ns*, 156 F.3d at 1186 (rejecting a construction that would import a limitation from the specification and acknowledging the Federal Circuit's "repeated statements that limitations from the specification are not to be read into the claims").

Contrary to Plaintiffs' arguments, the prosecution history additionally makes clear that Patentee intended for the phrase "in need of" to be used to define the relevant patient population.

During the prosecution of the '600 patent, the examiner initially rejected a similar limitation "in need of an improved cosmetic appearance" as being overly broad and indefinite. Cipriano Decl., Ex. A at 6. The examiner explained that "the specification does not provide any definition of who [subjects in need of an improved cosmetic appearance] are." *Id.* The examiner reasoned that subjects "in need of an improved cosmetic appearance" is a broader group than subjects with red eyes. *Id.* As such, the examiner concluded that this term rendered the claims unpatentable under 35 U.S.C. § 112. *Id.*

In response, Patentee amended claim 1 to include the language "a human subject having ocular hyperemia" and "said human in need of said reduction of eye redness." Cipriano Decl., Ex. B at 2. Patentee explained that "[c]laim 1 has been amended to recite that the human has hyperemia in the eye." *Id.* at 6. Not that claim 1 had been amended to include an efficacy limitation. Patentee further amended "subjects in need of an improved cosmetic appearance" to "subject is in need of reduction of eye redness for the purpose of an improved cosmetic appearance." *Id.* at 2. Patentee stated that this amendment was made "to recite that reduction of redness is for the purpose of improving the cosmetic appearance of the eye." *Id.* at 7. At no point did Patentee associate these amendments with efficacy.

Defendants respectfully request that the Court disregard Plaintiffs' attempt to import an unsupported efficacy limitation ("where such hyperemia is reduced by vasoconstriction") into the construction and to adopt the part of the construction that the parties agree on—that said human "in need of said reduction of eye redness" is a human "having ocular hyperemia."

B. "as the sole active ingredient"

Claim Term for Construction	Defendants' Proposed Construction	Plaintiffs' Proposed Construction
"as the sole active ingredient" Claims 12, 28 (language appears in Claim 1, from which the Asserted Claims depend directly).	"without any other active ingredient in the ocular drop"	"[administering brimonidine] as the only active ingredient to affirmatively reduce redness in a person having ocular hyperemia"

The plain language of the claim makes clear that brimonidine is "the sole active ingredient" *within the ocular drop*. Nowhere in claim 1 does the language of Plaintiffs' proposed construction—"as the only active ingredient to affirmatively reduce redness in a person having ocular hyperemia" appear. Instead, Plaintiffs must rely on statements made during prosecution, stripped of their proper context, to argue the propriety of their construction.

Plaintiffs' proposed construction improperly disregards the plain language of the claim because it would read out of the claim the limitation that there be "**an ocular drop comprising** about 0.025% weight by volume brimonidine as the sole active ingredient." "When the language of a claim is clear, as here, and a different interpretation would render meaningless express claim limitations, [courts should] not resort to speculative interpretation based on claims not granted." *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950–51 (Fed. Cir. 2006) (quoting *Unique Concepts, Inc. v. Brown*, 939 F.2d 1558, 1563 (Fed. Cir. 1991)). That is the case here.

Plaintiffs claim that "Patentee clearly and unmistakably surrendered and disclaimed the use of brimonidine with any other active agent and limited the claimed method to using brimonidine as the sole active ingredient to distinguish prior art (Dean) and induce the patent grant." Pl. Br. at 23. [1] That is not so. The standard for disclaimer is high—the alleged

[1] Plaintiffs' position suggests that the examiner's silence with respect to Dean is tantamount to accepting Patentee's arguments, but the inference that Plaintiffs ask the Court to make here is

disavowing statements must be "so unmistakable as to be unambiguous evidence of disclaimer." *Omega*, 334 F.3d at 1325. "The burden to show prosecution disclaimer is high because claim terms are entitled to a heavy presumption that they carry their ordinary and customary meaning to those skilled in the art in light of the claim term's usage in the patent specification." *Saffran v. Johnson & Johnson*, 712 F.3d 549, 570 (Fed. Cir. 2013) (cleaned up); *see also Avid Tech., Inc. v. Harmonic, Inc.*, 812 F.3d 1040, 1045 (Fed. Cir. 2016) (reversing district court's finding of prosecution disclaimer and explaining that "[w]hen the prosecution history is used solely to support a conclusion of patentee disclaimer, the standard for justifying the conclusion is a high one."); *AstraZeneca AB v. Andrx Lab'ys, LLC*, Civ. No. 14-8030-MLC-DEA, 2017 WL 111928, at *43 (D.N.J. Jan. 11, 2017) ("the isolated statements identified by Perrigo do not meet the high standard for prosecution disclaimer to attach"); *Chemours Co. FC, LLC v. Daikin Indus., Ltd.*, Civ. No. 17-1612-MN-CJB, 2022 WL 855518, at *9 (D. Del. Mar. 23, 2022) (rejecting prosecution disclaimer argument and explaining that "the standard for justifying the conclusion is a high one"); *St. Clair Intellectual Prop. Consultants, Inc. v. Acer, Inc.*, Civ. No. 09-354-LPS, 2012 WL 3536454, at *6 (D. Del. Aug. 7, 2012) (rejecting prosecution disclaimer argument because "Defendants have failed to meet the high standard for establishing a prosecution disclaimer").

Here, Plaintiffs have failed to satisfy their high burden to show that Patentee's arguments raised during prosecution provide a clear, unmistakable disclaimer of the use of other active ingredients. Plaintiffs ignore the context in which Dean was raised as prior art during

improper. *See Prima Tek II, LLC v. Polypap, S.A.R.L.*, 318 F.3d 1143, 1151 (Fed. Cir. 2003) ("We note that drawing inferences of the meaning of claim terms from an examiner's silence is not a proper basis on which to construe a patent claim"). As such, it is improper to assume that the examiner agreed with any of Patentee's characterizations of Dean.

prosecution of the '600 patent and cherry-pick statements that, when read in context, are not unambiguous disclaimers. The Federal Circuit has explained that "[w]hen determining whether disclaimer applies, we consider the statements in the context of the entire prosecution. If the challenged statements are ambiguous or amenable to multiple reasonable interpretations, prosecution disclaimer is not established." *Technology Props. Ltd. LLC v. Huawei Techs. Co., Ltd.*, 849 F.3d 1349, 1357–58 (Fed. Cir. 2017).

Considering the discussion of Dean in the context of the prosecution of the '600 patent, Patentee distinguished Dean in an effort to argue that Dean would not have motivated a POSA reading other prior art to use low-dose brimonidine to reduce eye redness. During prosecution, the examiner rejected the proposed claims of the '600 patent, in relevant part, because "it would have been *prima facie* obvious for a person of ordinary skill in the art to reduce eye redness in a patient in need thereof comprising the administration of a composition comprising diluted brimonidine as taught by Gil." Cipriano Decl., Ex. A at 11. According to the examiner, "the skilled in the art will be motivated to use lower concentrations of brimonidine, since Dean teaches that lower concentrations of brimonidine cause less side effects like hyperemia." *Id.* As the examiner explained, "Gil teaches . . . [t]he ability of an ophthalmic solution of brimonidine (**as the only active ingredient**) at concentrations ranging from 0.01% to 0.5% to reduce the neurogenic response (i.e. redness)." *Id.* at 10 (internal quotations omitted and emphases modified). The examiner cited to Dean to support the conclusion that Dean would have motivated a POSA to use concentrations of brimonidine that were on the lower end of the range taught by Gil. *Id.* at 11.

Patentee's response to the examiner's rejection should be read in that context—that the prior art taught the use of brimonidine as the sole active ingredient to reduce eye redness and that

Dean provided motivation for a POSA to use low-dose brimonidine. In that context, Patentee was arguing that Dean would not have provided motivation because "Dean is not directed to treating eye redness, nor does it suggest using brimonidine, let alone low-dose brimonidine as the sole active ingredient, to affirmatively reduce eye redness in a patient having ocular hyperemia." Cipriano Decl., Ex. B at 13. In other words, Patentee was arguing that Dean's use of "*combinations* of brinzolamide and brimonidine for treating a different condition, i.e., lowering intraocular pressure (IOP)" would not have motivated a POSA to lower the dose of brimonidine that Gil used. *See id*. (emphasis original). The obviousness rejection did not turn on whether Dean taught the use of one or multiple active ingredients—it turned on whether Dean would have motivated a POSA to use the lower dosing range of the brimonidine drops disclosed by Gil to reduce redness.

This context is confirmed by other statements made by Patentee in the paragraphs immediately following the ones Plaintiffs selectively cited to in their brief. Patentee argued that "[n]othing in Gil or Dean teach or suggest to a skilled artisan that brimonidine—a drug known to *cause* hyperemia—would work to reduce hyperemia at about 0.025%, as claimed here." *Id.* at 14 (emphasis original). According to Patentee, "if *anything*, the art suggested that a skilled artisan would *raise* the concentration of brimonidine to take advantage of its minimal α-1 effect, if the artisan were interested in using brimonidine for treating hyperemia." *Id.* (emphases original). Calling it "an important distinction," Patentee argued that Dean, regardless of one or multiple active ingredients, "suggests that *lowering* the dose of brimonidine may *induce* less redness (as a side effect), but does not teach or suggest *reducing redness* in a subject *having* ocular hyperemia." *Id.* at 13 (emphases original). Patentee's argument that Dean does not teach a POSA to use low-dose brimonidine was directed at whether Dean provided motivation and not

how the claims were defined over Dean. As such, Patentee's statements do not meet the high bar to constitute prosecution history disclaimer. *See Kangaroo Media, Inc. v. YinzCam, Inc.*, Civ. No. 2:12-cv-00382-JFC, 2013 WL 8812587, at *67 (W.D. Pa. Feb. 5, 2013) (finding no prosecution history disclaimer where "the patentees in the foregoing arguments were arguing that the PTO had not made a *prima facie* case of obviousness because there was no motivation to make the modifications to [the prior art]. The patentees were not arguing how their claims defined over [prior art].").

Plaintiffs' claim that brimonidine is "the sole active agent in the claimed method"—rather than in the ocular drop—is further called into question by the '600 patent specification. For example, in a section entitled "Combination Treatments," the '600 patent provides for methods "using low doses of highly selective α-2 agonists by themselves, [and] for using these highly selective α-2 agonists in several combinatorial applications, for example in combinations with α-1 antagonists and in combinations with antihistamines." '600 patent at 15:61–67. The '600 patent explains that "compositions and methods of the present invention may combine highly selective α-2 agonists . . . with α-1 antagonists and/or selective α-1 antagonists to minimize hyperemia." '600 patent at 16:10–19. The '600 patent also explains that "[i]n another embodiment, the invention generally relates to a composition formulated for treating and/or preventing an allergic response with reduced rebound hyperemia." '600 patent at 16:29–37.

While Plaintiffs now argue that Patentee intended to draft something different than what was actually claimed, "it is not the province of the courts to salvage poorly—or incorrectly—drafted patent claims." *Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp.*, 493 F.3d 1358, 1368 (Fed. Cir. 2007). Defendants' proposed construction is true to the plain language of the claim and most naturally aligns with the specification. As the Federal Circuit has explained,

"[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Phillips*, 415 F.3d at 1316 (internal quotations omitted). As such, the Court should construe "as the sole active ingredient" to mean "without any other active ingredient in the ocular drop" as Defendants propose.

IV. CONCLUSION

For at least the foregoing reasons, Defendants respectfully request that the Court adopt Defendants' proposed constructions and reject Plaintiffs' proposals.

Dated: December 20, 2023

/s/ Louis H. Weinstein

Louis H. Weinstein
WINDELS MARX LANE & MITTENDORF LLP
One Giralda Farms
Madison, NJ 07940
(973) 966-3200
lweinstein@windelsmarx.com

Attorneys for Defendants Slayback Pharma LLC, Slayback Pharma India LLP, Dr. Reddy's Laboratories S.A., and Dr. Reddy's Laboratories, Inc.

OF COUNSEL:

Robert Frederickson, III (*pro hac vice*)
Elaine Herrmann Blais (*pro hac vice*)
GOODWIN PROCTER LLP
100 Northern Avenue
Boston, MA 02210
(617) 570-1000
rfrederickson@goodwinlaw.com
eblais@goodwinlaw.com

Linnea Cipriano (*pro hac vice*)
Timothy J. Beavers (*pro hac vice*)
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018
(212) 813-8800
tbeavers@goodwinlaw.com
lcipriano@goodwinlaw.com

Christopher Cassella (*pro hac vice*)
GOODWIN PROCTER LLP
1900 N Street NW
Washington, DC 20036
(202) 346-4358
ccassella@goodwinlaw.com

CERTIFICATE OF SERVICE

I, Louis H. Weinstein, hereby certify that I served Defendants' Responsive *Markman* Submission, the Declaration of Linnea P. Cipriano, and Exhibits A and B, on Plaintiffs counsel via ECF and email on December 20, 2023.

/s/ Louis H. Weinstein
Louis H. Weinstein
WINDELS MARX LANE & MITTENDORF LLP
One Giralda Farms
Madison, NJ 07940
(973) 966-3200
lweinstein@windelsmarx.com